

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (870.2400, formerly §81-4)

Product Manager: 23
MRID No.: 45086101

Reviewer: Byron T. Backus, Ph.D.
Amended Report Date: March 30, 2000
Study No.: 00-0661-G1

Testing Facility: Toxikon Corporation, Bedford, MA 01730
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Quality Assurance (40 CFR §160.12): Included (p. 6)

Test Material: Admiral WSP; Lot/Batch #: 10673; a dark blue powder

Dosage: 0.1 mL

Species: Rabbits; New Zealand White

Age: Adult (at least 10 weeks old)

Weight: 2.21-2.27 kg

Source: Millbrook Breeding Labs, Amherst, MA

Conclusion:

1. **Toxicity Category:** III [see special comment, below]
2. **Classification:** Acceptable

Procedure (including deviations from 870.2400): "Three animals were treated by instilling 0.1 mL of the test article in the left eye of each animal. The right eye was left untreated to serve as control."

"The eyes of the test animals were not washed out for 24 hours following installation of the test substance. After the 24 hour reading, all eyes were washed with 0.9% USP Sodium Chloride for Injection (NaCl)."

Observations	Number "positive"/number tested			
	Hours			
	1	24	48	72
Corneal Opacity	0/3	0/3	0/3	0/3
Iritis	0/3	0/3	0/3	0/3
Conjunctivae:				
Redness ^a	0/3	0/3	0/3	0/3
Chemosis ^a	0/3	0/3	0/3	0/3

^aScore of 2 or more considered to be "positive."

Data summarized from Tables II-A, II-B & II-C, pp. 16-18 of MRID 45086101.

Summary: From p. 13: "Slight irritation was observed in all the treated eyes 1 hour after dosing. This irritation was resolved in all the treated eyes by the 48 hour observation point." However, it is stated on p. 14 that: "No signs of irritation were noted in the treated eyes or control eyes at any of the observation points." [The latter statement is consistent with the eye scoring observations, summarized in the table above.]

Special Comment: There appear to be some inconsistencies in the reporting of this study, as indicated in the summary above. Because of these apparent inconsistencies, TRB is recommending (on the basis of the worst-case scenario) that the product be assigned to toxicity category III in terms of its eye irritation potential. In order to reclassify this product to toxicity category IV, an adequate clarification of these apparent inconsistencies in MRID 45086101 should be made.